K103336

FLUKE Biomedical

Section III -510(k) Summary of Safety and Effectiveness

APR 13 2011

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Submitter:

Fluke Biomedical
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John Nelson –Contact Person

Device Name:

- Trade Name - MPS450 Multiparameter Simulator
- Common Name –Simulator
- Classification Name - Cardiac monitor (including cardiotachometer and rate alarm), per 21 CFR § 870.2300
- Product Codes -DRT

Devices for Which Substantial Equivalence is Claimed:

- MedSim300B

Device Description:

Principles of Operation

Fluke Biomedical's MPS450 Multiparameter Simulator (hereafter referred to as the MPS450) provides a basis to train, evaluate, and perform preventive maintenance for virtually all patient monitors found in the healthcare industry. This is accomplished with multiple physiological simulations for ECG, blood pressure, respiration, temperature, pacemaker, artifact, and arrhythmia conditions. The MPS450 is a lightweight, battery powered unit that is portable enough to test a patient monitor anywhere the monitor is being used.

Technological Characteristics

The MPS450 consists of the following components:

1) Printed Circuit Board Assemblies using surface mount components and firmware loaded in embedded processors.
2) Plastic injection molded case parts.
3) Liquid Crystal Display for user interface.
4) Two 9 V alkaline batteries for portable operation, giving user flexibility and portability.

Intended Use of the Device:

The MPS450 Multiparameter Simulator is an electronic signal source for determining that patient monitors are performing within their operating specifications.

The MPS450 provides the following function categories:

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ECG Functions
Arrhythmia Functions
ECG-Performance Testing
Respiration
Blood Pressure
Temperature
Cardiac Output (Optional)
Fetal/Maternal ECG & IUP (Optional)

The intended user is a trained biomedical equipment technician, who is performing periodic preventative maintenance checks on patient monitors in service. Users can be associated with Hospitals, clinics, original equipment manufacturers, and independent service companies that repair and service medical equipment. The end user is a technically trained individual, specializing in medical instrumentation technology.

MPS450 is intended to be used in the laboratory environment and is not intended for use on patients, or to test devices while connected to patients.

This device is not to replace clinical testing of waveform detecting devices such as patient monitors.

MPS450 is intended for over-the counter use.

Summary of Technological Characteristics:

MPS450 is substantially equivalent to another legally marketed device in the United States. MPS450 functions in a manner similar to and is intended for the same use as MedSim300B that is currently marketed by Fluke Biomedical.

Features	MPS450	MedSim 300B (K935817)	Difference
Intended Use	To test operation of patient monitors by simulating physiological parameters, including: ECG, respiration, blood pressure, temperature and cardiac output	To test operation of patient monitors by simulating physiological parameters, including: ECG, respiration, blood pressure, temperature and cardiac output	None
Device Description			
Physical characteristics.			
construction	Plastic case	Aluminum case	Lighter
Size	7.5 L x 6 W x 2 H inches	10 L x 7 W x 3 H inches	Smaller
Weight	1lbs 8 oz	3.55 lbs	Lighter
Operating panel characteristics			
Display	4 by 20 character LCD	2 by 24 character LCD	More lines on display of MPS450
ECG leads	10 binding posts; compatible w/ disposable snaps, 3.2 mm or 4.0 mm electrodes, and banana plugs.	10 binding posts; compatible w/ disposable snaps, 3.2 mm or 4.0 mm electrodes, and banana plugs.	None

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High level ECG	0.2 V/mV +/- 5% of the ECG amplitude setting available on the BP3 connector	¼" standard phone jack w/ lead II waveform at .2V/mV of ECG lead II signal. Use w/ analog input, high level, central station monitors or recorders	Different type of connector- same functionality
BP Channels	4 independent BP channels w/ sensitivity control (5 or 40 uV/V/mmHg); cable interface w/ monitors	4 independent BP channels w/ sensitivity control (5 or 40 uV/V/mmHg); cable interface w/ monitors	None
Respiration	Baseline Impedance (500 – 2000) control; lead select control	Baseline Impedance (500 – 2000) control; lead select control	None
Temperature	Yes, fixed temp. probe select control (400 or 700 YSI) series probes	Yes, fixed or variable temp. probe select control (400 or 700 YSI) series probes	Fixed temp probe use only for MPS450
Cardiac output	Yes, cable connect w/ monitor	Yes, cable connect w/ monitor	None
RS -232 port	Yes	Yes	None
Battery test	No	Yes, 8.4V or 9V, low battery signal if < 6.2V	Not needed by customers in MPS 450- a "nice to have, but not Must have feature"
Lead test	No	Yes	Same as above- not a needed feature on MPS 450
Function Key control	Yes	Yes	None
Power	2 X 9V alkaline batteries w/ low battery indicator; or battery eliminator (115VAC) transformer certified to CSA C22.2. 231 series M89)	2 X 9V alkaline batteries w/ low battery indicator; or battery eliminator (115VAC) transformer certified to CSA C22.2. 231 series M89)	None

Functional Operation

ECG simulation			
Lead configuration	12 Leads	12 leads	None
Output impedances	500 to 2000ohms to RL	500 to 2000ohms to RL	None
Amplitude accuracy	+/- 2% setting lead II	+/- 5%, 2Hz @ 1.0 mV p-p SQ wave Lead II	More accurate in MPS 450
NSR rates	30 to 300 bpm	30 to 300 bpm	None
NSR amplitudes	50 uV to 5.5mV	50 uV to 5.5mV	None
ST Segments	-0.8 to + 0.8 mV	-0.8 to + 0.8 mV	None
Axis deviation	No	Normal, horizontal and vertical	Feature not needed by end-user customers
Pediatric ECG	Yes, R Wave width reduced to 40 ms	Yes, R Wave width reduced to 40 ms	None

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Performance testing			
Square wave	2 Hz, 0.125 Hz	2 Hz	2 selections rather than 1 in MPS 450
Pulse	60ms	4.0 sec.	Faster pulse in MPS450
Sine waves	Various -0.5 to 100 Hz	Various -0.05 to 1000 Hz	Only narrower range of sine waves needed in MPS450
Triangle wave	2 Hz and 2.5Hz	2 Hz	2 selections in MPS450
R Wave detector	Yes	Yes	None
Pacemaker	Yes, 0.1 to 2.0 msec pulse duration, -10 to +10 mV pulse amplitude	Yes, 0.1 to 2.0 msec pulse duration, -700 to +700 mV pulse amplitude	Pacer pulse amplitude lower for MPS450-testing at lower level than Medsim300
Premature beat insertion	Yes, PVC, PNC or PAC	Yes, PVC, PNC or PAC	None
Cable connector	ECG leads, 10 binding postings	ECG leads, 10 binding postings	None
Respiration simul.			
Normal baseline impedances	500 to 2000 ohms ref. to RL	500 to 2000 ohms ref. to RL	None
Lead selections	LA or LL	I, II, and RL-LL	Reference ECG leads only 2 choices in MPS 450
Impedance variation	0.2, 0.5, 1.0, and 3.0 ohms	0, 0.1, 0.2, 0.5, 1.0, and 3.0 ohms	Simplified selection of Impedance variables in MPS450
Respiration rates	15, 20, 30, 40, 60, 80, 100, 120 brpm	15, 20, 30, 40, 60, 120 brpm	Added 80 and 100 brpm in MPS450
Apnea	Off, continuous, momentary, 12, 22 & 32 s	Off, continuous, momentary, 12 & 32 s	Added 22 second Apnea in MPS450
Cable connector	ECG leads, binding posts	ECG leads, binding posts	None
Cardiac output	Yes	Yes	None
Catheter size	Fixed, 7F injectate vol. 10 cc	Fixed, 7F injectate vol. 10 cc	None
Blood temperatures	37.0	36.0 to 38.0C; and user programmable	Single selection for temp. of blood in cardiac output.
Injectate temp	Chilled (0C) or 24 C	Chilled (2C)	2 selections for injectate temp.
Fixed blood flow rate	2.5, 5, 10 L/min	3, 5, 7 L/min	Selection of blood flow rates widened in MPS 450
Curves	Normal, faulty and L/R shunt	Normal, interrupt, slow, L/R shunt	Different curves for simulating different cardiac flow conditions in MPS 450
Output trend	No	1 normal, 2 defective	Feature not needed by customers in MPS450

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Bath/Injectate resistance	Continuously variable, 3 pin standard	Continuously variable, 3 pin standard	None
Cable connector			
- Blood temp	American Edward, 3 pin standard	American Edward, 3 pin standard	None
- Injectate Temp	American Edward, 4 pin standard	American Edward, 4 pin standard	None
Blood pressure			
I/O impedance	300 ohms	300 ohms	None
Exciter range	2 to 16 V/DC to 5kHz	2 to 16 V/DC to 4 kHz	Higher frequency in MPS450.
Transducer Sensitivity	5 or 40 uV/V/mmHg	5 or 40 uV/V/mmHg	None
Level accuracy	+/- (2% setting + 2mmHg)	+/- 1% full scale; +/- 1mmHg	Different ranges on MPS 450 resulted in different accuracy specification
Static pres. Selection	Manual	Manual and automatic	Only Manual in MPS450
BP selections			
- Dynamic	Arterial, Radial artery, left and right ventricle, pulmonary artery, pulmonary wedge, right atrium, left atrium and Swan-Ganz	Arterial, left and right ventricle, pulmonary artery, pulmonary wedge, Swan-Ganz	More BP simulation types in MPS450
- Static	-10, -5, 0, 20, 40, 50, 60, 80, 100, 150, 160, 200, 240, 320 and 400 mmHg	-10, -5, 0, 20, 30, 40, 80, 100, 200, 250, 300 mmHg	More static IBP pressures simulated in MPS450
- Cable connector	Mini-DIN	DIN style	Different connector uses different set of IBP cables- mini-DIN is smaller, but DIN style is more rugged.
Temperature Simulation	Mini-DIN	DIN Style	Different connector uses different set of IBP cables- mini-DIN is smaller, but DIN style is more rugged.
- Temperature	0, 24, 37 and 40C	34, 37, 40C	Additional temp simulation points in MPS450
- Dynamic trends	No	Hypothermia, spike and hyperthermia	Feature not implemented in MPS450- not useful to end user customers.
Probe compatibility	Series 400 and 700	Series 400 and 700	None

Cable connector	Mini-Din	DIN Style	Different connector uses different set of IBP cables- mini-DIN is smaller, but DIN style is more rugged.

Substantial Equivalence:

The *MPS450* is substantially equivalent to one other legally marketed device in the United States. The *MPS450* functions in a manner similar to and is intended for the same use as the *MedSim300B* manufactured by Fluke Biomedical.

The MPS450 is similar to the *MedSim300B* in that it is a cordless battery-operated device, uses LCD display, and allows user to simulate physiological parameters to verify the operation of patient monitors. The *MPS450* differs from the *MedSim300B* in that the *MPS450* is lighter, smaller does not contain a battery test feature, improved accuracy and a wider range of performance testing characteristics than the MedSim300B.

Non-Clinical Test Data:

Laboratory studies have been conducted with a representative patient monitor to verify and validate the MPS450 will perform within its' published specifications –Document: NPI-10292010-00002

The *MPS450* software has been successfully validated to confirm the performance of the device. Document: NPI-10292010-00002 and NPI-11012010-00001

Clinical Test Data:

Clinical testing has not been conducted on this product.

Conclusion:

Based upon the laboratory studies, similar technological/performance characteristics as compared to the predicate device, and successful validation of the *MPS450* software, the performance of the *MPS450* is deemed to be substantially equivalent to the *MedSim300B.*

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Fluke Biomedical
c/o Mr. John Nelson
Director of Regulatory/Quality Affairs
6045 Cochran Rd.
Solon, OH 44139

APR 13 2011

Re: K103336
Trade/Device Names: MPS450 Multiparameter Simulator
Regulatory Number: 21 CFR 870.2300
Regulation Name: Cardiac Monitor (including Cardiotachometer and Rate Alarm)
Regulatory Class: Class II (Two)
Product Code: DRT
Dated: March 24, 2011
Received: April 4, 2011

Dear Mr. Nelson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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Indications for Use

510(k) Number (if known): K103336

Device Name: MPS450 Multiparameter Simulator

Indications for Use:

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The MPS450 provides the following function categories:

ECG Functions
Arrhythmia Functions
ECG-Performance Testing
Respiration
Blood Pressure
Temperature
Cardiac Output (Optional)
Fetal/Maternal ECG & IUP (Optional)

Prescription Use _____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use ____X___ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
for Division of Cardiovascular Devices

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510(k) Number K103336